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In re Application of :  
Goodnow et al :  
Serial No.: 10/735,991 : DECISION ON PETITION  
Filed: 15 December 2003 :  
Attorney Docket No.: 21366 :

This letter is in response to the Petition under 37 C.F.R. 1.144, filed 27 December 2005, requesting review of the restriction requirement originally set forth in the communication mailed 12 May 2005 and made FINAL in the first Office action on the merits mailed 15 August 2005.

#### BACKGROUND

This application was filed under 35 U.S.C. 111 on 15 December 2003, and contained claims 1-36. On 12 May 2005 the examiner mailed to applicants a restriction requirement in which the 36 claims were divided into 14 groups, as follows:

Group I, claims 1, 3, 5, 14, 19, 25, 28, 30 and 33, drawn to a method of identifying compounds by contacting a test compound with a mammalian sequence #115;

Group II, claims 2, 4, 6, 15, 22, 26, 29, 31 and 34, drawn to a method of identifying compounds by contacting a sequence #115 ligand with a mammalian sequence #115;

Group III, claims 7-8, 16, 27 and 32, drawn to a method for identifying compounds by contacting a test cell with a mammalian sequence #115 and measuring cAMP levels;

Group IV, claims 7, 9, 16, 27 and 32, drawn to a method for identifying compounds by contacting a test cell with a mammalian sequence #115 and measuring cytoplasmic  $\text{Ca}^{+2}$  levels;

Group V, claims 7, 10-11, 16, 27 and 32, drawn to a method for identifying compounds by contacting a test compound with a cell expressing a mammalian sequence #115 and measuring the expression of a reporter gene;

Group VI, claims 7, 12, 16, 27 and 32, drawn to a method for identifying compounds by contacting a test compound with a cell expressing mammalian sequence #115 and measuring inositol 1,4,5-triphosphate levels;

Group VII, claims 7, 13, 16, 27 and 32, drawn to a method for identifying compounds by contacting a test cell with mammalian sequence #115 and measuring 1,2-diacylglycerol levels;

Group VIII, claims 17-18, drawn to a pharmaceutical formulation that modulates the activity of mammalian sequence #115;

Group IX, claim 20, drawn to a method of treating obesity comprising administering compounds which modulate the activity of mammalian sequence #115;

Group X, claim 21, drawn to a method of treating cachexia by administering a composition that binds to sequence #115;

Group XI, claim 23, drawn to a method of treating obesity by administering a pharmaceutical composition which alters the binding of sequence #115 to the mammalian sequence #115;

Group XII, claim 24, drawn to a method of treating cachexia by administering a pharmaceutical composition which alters the binding of sequence #115 to mammalian #115;

Group XIII, claim 35, drawn to an antibody that recognizes SEQ ID NO: 6;

Group XIV, claim 36, drawn to an antibody that recognizes SEQ ID NO: 5.

Appropriate arguments for distinctness between groups were set forth.

On 9 June 2005 applicants responded to the restriction requirement by provisionally electing with traverse Group I, claims 1, 3, 5, 14, 19, 25, 28, 30, and 33, and arguing lack of burden on the Office among other things.

On 15 August 2005 the examiner mailed to applicants a first Office action on the merits in which the examiner acknowledged the election and replied to the traversal of the restriction requirement and made the requirement FINAL. The application was objected to for lack of sequence compliance and claims 1, 3, 5, 14, 19, 25, 28, 30 and 33 were rejected under 35 U.S.C. 112, second paragraph, as indefinite for various reasons. The claims were also rejected under 35 U.S.C. 112, first paragraph, for lack of enablement and lack of written description. The claims were further rejected under 35 U.S.C. 102(b) as anticipated by Glucksmann et al and under 35 U.S.C. 102(e) as anticipated by Liaw et al.

On 15 December 2005 applicants filed an amendment in response to the Office action in which applicants replaced the term "mammalian #115" with SEQ ID NO. 6 indicating that this is the amino acid sequence of the human protein. SEQ ID NO. 5 was indicated to be the nucleic acid sequence encoding said human protein of SEQ ID NO. 6.

On 21 December 2005 applicant filed a supplemental amendment in which they resubmitted two figures and the sequence listing to comply with the requirements of 37 C.F.R. 1.821 - 1.825.

On 27 December 2005 applicants filed this Petition under 37 C.F.R. 1.144 requesting Director review of the restriction requirement.

## DISCUSSION

Applicants traverse the examiner's restriction requirement on the basis of three central points.

### **(1) All Groups are Related and Classified in the Same Class and Subclass**

Applicants emphasize that all of the 14 groups into which the examiner has restricted the original 36 claims are classified in exactly the same class and subclass: Class 514, subclass 44.

Applicants note that while the examiner stated that the inventions are unrelated because they have different modes of operation, different functions, different effects, a review of the claims shows that most, if not all, of the claims are related. Applicants especially note that each of the claims requires the use of the same mammalian sequence #115.

Applicants' arguments have been fully considered and are deemed persuasive in part. In and of itself, the classification of inventions in the same class and subclass does not determine whether inventions are independent and distinct or not. It is but one factor which is weighed in the determination of whether inventions are independent and distinct. However, in the instant fact situation it appears that the assays defined by independent claims 1 and 7 are so related that a reference disclosing one method could more likely than not be used to show the other method to be obvious since the same mammalian sequence #115 is used in each method. Furthermore, the use of a purified protein or the use of a cell expressing said protein would normally be considered obvious variations of the method. The measurement of cAMP or cytoplasmic calcium or cAMP responsive element are routine assays for measuring the effect of ligands and test compounds on G-protein coupled receptors.

## **(2) The Examiner Has Already Performed a Search Covering Most Groups**

Applicants argue that by performing a sequence search of mammalian sequence #115 (nucleic acid search) combined with a text search of G-protein coupled receptors, the examiner has already effectively searched most of the identified groups.

This argument has been fully considered and is deemed persuasive. The key element of each of the different groups defining a method requires the use of the same mammalian sequence #115. However, it was unclear to the examiner whether or not sequence #115 was a protein or polynucleotide sequence. Therefore, the examiner performed a sequence search of SEQ ID NO. 5, the polynucleotide, only.

## **(3) Maintaining the Restriction Requirement Would Be Unfair to Applicants**

Applicants urge that it would be quite unfair to them if they had to file 13 divisional applications and pay over \$135,000 in filing-associated fees, issue fees, and maintenance fees alone to prosecute, obtain, and maintain 13 divisional patents on all the pending claims in the current application. Applicants' argument has been fully considered but is not directed to the merits of whether the claimed inventions are independent and/or distinct and is, therefore, dismissed

## **DECISION**

For the above reasons the Petition is **GRANTED-IN-PART**.

The restriction requirement set forth is modified, as follows:

Group I, claims 1, 3, 5, 7-14, 16, 27, 30 and 32, directed to a method of identifying compounds useful for modulating body weight comprising the use of a polynucleotide having 85 % homology with SEQ ID NO. 5;

Group II, claims 1, 3, 5, 7-14, 16, 27, 30 and 32, directed to a non-competitive method of identifying compounds useful for modulating body weight comprising the use of a protein having 85% homology with SEQ ID NO. 6;

Group III, claims 2, 4, 6, 15, 26, 29, 31 and 34, directed to a competitive method for identifying compounds useful for modulating body weight comprising the use of a protein having 85% homology to SEQ ID NO. 6;

Group IV, claims 2, 4, 6, 15, 26, 29, 31 and 34, directed to a competitive method for identifying compounds useful for modulating body weight comprising the use of a polynucleotide having 85% homology to SEQ ID. NO. 5;

Group V, claims 17-19, 22, and 33 - 34, directed to a weight modulating pharmaceutical composition and method for preparing same;

Group VI, claims 20 and 23, directed to a method for treating obesity;

Group VII, claims 21 and 24, directed to a method for treating cachexia;

Group VIII, claims 35 - 36, directed to an antibody against the polypeptide of SEQ ID NO. 5.

Applicants' election of previous Group I is maintained as effective for Group I, as now modified, and all claims of Group I will be considered by the examiner in preparing the next Office action. The application will be forwarded to the examiner for consideration of applicants' reply filed 15 December 2005.

Any request for reconsideration of this decision must be filed within two (2) months of the mailing date of this decision in order to be considered timely.

Should there by any questions regarding this decision, please contact Special Program Examiner, William R. Dixon, Jr. by letter addressed to Director, TC 1600, at the address listed above, or by telephone at 571-272-0519 or by facsimile sent to the general Office facsimile number, 571-273-8300.



George C. Elliott  
Director, Technology Center 1600